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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,676	02/28/2002	Iris Ziegler	148/50932	2539

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/20/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/084,676

Applicant(s)

ZIEGLER ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time and amendment A filed 07/28/03. Claims 17 and 38 are pending.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. It is noted that a translation of the priority document is not provided. Applicants cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1-38 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the amendment.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claims 1-11, 13, 22 and 23 under 35 U.S.C. 102(b) as being anticipated by Betzing et al. (US 5,776,492) is withdrawn in light of the amendment.

4. The rejection of claims 1-8, 10-13, 19, 21, 22, 25 and 26 under 35 U.S.C. 102(b) as being anticipated by Raffa (US 5,516,803) is withdrawn in light of the amendment.

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5. The rejection of claims 1-8, 10, 11, 13, 19, 20, 22, 24 and 26 under 35 U.S.C. 102(e) as being anticipated by Oshlack et al. (US 5,958,452) is withdrawn in light of the amendment.

6. The rejection of claims 1-8, 10, 19, 20, 22, 24 and 26 under 35 U.S.C. 102(a) as being anticipated by Oshlack et al. (US 5,958,452) is withdrawn in light of the amendment.

7. Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Mauskop (US 5,914,129).

Mauskop discloses magnesium containing analgesic oral composition for the treatment/alleviation of pain, and specifically migraine headache pain (abstract). Solid formulations of the composition are capsules, catchets or tablets and powder or granules; liquid formulations are solution or suspension in aqueous liquid or non-aqueous liquid and oil-in-water or water-in-oil emulsions; and solid formulation of tablet and capsules are preferred with tablet being the most preferred (column 6, lines 12-21). In a particular embodiment of Mauskop, the magnesium containing analgesic composition includes at least two different non-opioid analgesic agents, at least two different opioid analgesic agents or at least one non-opioid analgesic agent and at least one opioid analgesic agent and it is believed that a combination of non-opioid analgesic agents or opioid analgesic agents or a combination of non-opioid and opioid analgesic agents act synergistically to relieve pain (column 3, lines 47-54). In the case where the pharmaceutical composition comprises a combination of a non-opioid analgesic agent and an opioid analgesic agent (claim 6); the non-opioid analgesic agent of ibuprofen, naproxen and diclophenac (diclofenac sodium) are included in the list of non-opioid analgesic agents provided (claims 1-4, 6 and 15) and the opioid analgesic agents of tramadol is included in the list of opioid analgesic agents provided (claims 1, 4, 5, 6 and 17). Mauskop, in column 6, lines 18-31,

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discloses how the tablet is formulated. Mauskop discloses a combination of opioid analgesic and non-opioid analgesic to synergistically act to relieve pain and tramadol and diclofenac are included in the list provided. The property of a composition is not separable from the composition and how a composition is made is not critical. The teaching of Mauskop meets the limitations of the instant claim.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
9. The rejection of claims 9 and 20 under 35 U.S.C. 103(a) as being unpatentable over Raffa (US 5,516,803) is withdrawn in light of the amendment.
10. The rejection of claims 27-37 under 35 U.S.C. 103(a) as being unpatentable over Raffa (US 5,516,803) in view of known method of making tablets described in eighteenth edition of Remington's Pharmaceutical Sciences, 1990, pages 1641-1647 is withdrawn in light of the amendment.
11. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mauskop (US 5,914,129) in view of known method of making tablets described in eighteenth edition of Remington's Pharmaceutical Sciences, 1990, pages 1641-1647 is withdrawn in light of the amendment.

Mauskop discloses a composition comprising tramadol and diclofenac and a method of preparing the composition. Mauskop does not narrate the preparation of the composition as

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recited in the instant claim. However, a method of making compositions are disclosed and taught in the eighteenth edition of Remington's Pharmaceutical Sciences. Remington specifically teaches wet-granulation method, fluid-bed granulation method, dry-granulation method, direct compression and related granulation processes (pages 1641-1647). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the preparation of Mauskop by employing granulation methods disclosed in the eighteenth edition of Remington's Pharmaceutical Sciences, 1990, pages 1641-1647, since utilizing the disclosed methods in Remington is expected to produce tablets.

Double Patenting

12. Claim 17 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 11 of copending Application No. 10/016,130. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 17 is directed a composition comprising tramadol and diclofenac; claim 1 of the copending application teaches a composition that comprises tramadol and diclofenac. The solubility and the release rate recited in instant claim 17 are properties and the property of a composition is not separable from the composition. The instant claim 17 does not exclude separate subunits. Applicants argue that the co-pending application teaches separate subunits and the in the instant claim, diclofenac and tramadol are formulated together. This argument is not persuasive because the instant claim does not exclude separate subunits and it appears that the separate subunits are formulated as one unit for administration.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center 1600

